DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 12, 2015

GE Healthcare Finland Oy
% Joel Kent, M.S., RAC
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, MA 02492

Re: K150298
Trade/Device Name: Entropy Module, E-ENTROPY-01
Regulation Number: 21 CFR 882.1400
Regulation Name: Electroencephalograph
Regulatory Class: Class II
Product Code: OLW, OMC, ORT
Dated: September 28, 2015
Received: September 29, 2015

Dear Mr. Kent,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Enclosure

Indications for Use

510(k) Number (if known): _____ K150298_____

Device Name: ENTROPY MODULE, E-ENTROPY-01

Indications for use:

The GE Healthcare Entropy module, E-ENTROPY, and accessories are indicated for adult and pediatric patients older than 2 years within a hospital for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals.

The Entropy algorithm in the host monitor calculates the spectral entropies, Response Entropy (RE) and State Entropy (SE), which are processed EEG and FEMG variables. The Entropy measurement is to be used as an adjunct to other physiological parameters.

In adult patients, Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may be associated with a reduction of anesthetic use and faster emergence from anesthesia.
The Entropy module is indicated for use by qualified medical personnel only.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

In accordance with 21 CFR 807.92(c) the following summary of information is provided:

Owner/Contact/Date (807.92(a)(1)):

Date: 5 October 2015

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Device names (807.92(a)(2)):

Trade Name: ENTROPY MODULE, E-ENTROPY-01
Common/Usual Name: Electroencephalograph
Classification Names: 21 CFR 882.1400 Electroencephalograph

Classification Product Code: OLW, OMC, ORT

Predicate Device(s) (807.92(a)(3)):	K061907 Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY-00
Device Description (807.92(a)(4)):	GE Healthcare Entropy Module, E-ENTROPY is a single-width plug-in parameter module for GE Healthcare modular monitoring systems. EEG signals reflect the underlying state of brain activity. As a person falls asleep or is anesthetized, the brain function (activity) starts to decrease and becomes more orderly and regular. EEG changes from irregular to more regular patterns when anesthesia deepens. Similarly, frontal EMG quiets down as the deeper parts of the brain are increasingly saturated with anesthetics. Entropy measurement is based on processing of raw EEG and FEMG signals by using the Entropy algorithm, a GE application of Spectral Entropy. The algorithm is published: Viertiö-Oja H et al. Description of the Entropy algorithm as applied in the Datex-Ohmeda S/5 Entropy Module. (Acta Anaesthesiologica Scandinavica 2004; Volume 48: Issue 2:154-161, 2004). Entropy measures irregularity of EEG and FEMG. The GE Entropy measurement devices are responsible for EEG and FEMG signal acquisition, amplification, filtering and digitization and electrode impedance measurement. The Entropy algorithm in the host monitor calculates the spectral entropies, Response Entropy (RE) and State Entropy (SE). The Entropy Module, E-ENTROPY-01 uses the identical Entropy algorithm and accessories as the predicate device, S/5™ Entropy Module, E-ENTROPY-00 (K061907). Parameters calculated by the Entropy algorithm are: - Response Entropy, RE (range 0-100), is a fast reacting parameter, which measures EEG and FEMG in the frequency range 0.8 Hz to 47 Hz. Its reaction time is two seconds. It may give an indication of the patient's reaction to external stimuli, such as intubation and skin incision, if neuromuscular blocking agents are not used. - State Entropy, SE (range 0-91), is a more stable and robust parameter, which measures EEG in the frequency range of 0.8 Hz to 32 Hz. Its reaction time is 15

seconds. SE may be used to assess the effect of certain anesthetic drugs on the brain.

- Burst Suppression Ratio, BSR (range 0-100%), is defined as the percentage of time of suppressed (isoelectric, flat line) EEG periods during the last minute of observation. Emergence of burst suppression pattern may indicate very deep anesthesia, hypothermia or ischemia.

The Entropy Module, E-ENTROPY measures the EEG and FEMG signals by using a sensor placed on patient's forehead.

The Entropy Module, E-ENTROPY acquires the EEG and FEMG signals from the sensor and communicates them to the host device.

The Entropy Module, E-ENTROPY is a plug-in module that can be used with Datex-Ohmeda S/5™ modular patient monitors and GE Healthcare's CARESCAPE™ modular patient monitors. GE Healthcare purchased Datex-Ohmeda in 2003 and while some of the legacy branding may remain the new Entropy Module, E-ENTROPY-01 and the predicate Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY as well as monitors mentioned are all products of GE Healthcare.

The Entropy Module, E-ENTROPY performs electrode impedance measurement for all sensor leads at the same time in order to determine if they are functioning well enough to make the measurement. The electrode impedance is measured by applying a known current through the electrode and measuring the voltage drop over the electrode. This way the impedance of a single electrode can be determined.

The Entropy Module, E-ENTROPY does not calculate the entropy values itself. The Entropy algorithm resides in the host patient monitor.

The Entropy Module, E-ENTROPY does not trigger or issue any physiological or technical alarms by itself. All management of alarms is entirely performed by the host monitor based on calculated entropy values and status data received from the module, as well as on the alarm

condition data stored in the host device.

The Entropy Module, E-ENTROPY is designed to be used with a host system. The module itself does not alarm or display data. The current hosts (all with separate 510(k) clearances) for the new Entropy Module, E-ENTROPY-01 are:

• Datex-Ohmeda S/5™ Anesthesia Monitor (K092680)

• Datex-Ohmeda S/5™ Compact Anesthesia Monitor (K061185)

• GE Healthcare CARESCAPE™ B850 Patient monitor (K131414)

• GE Healthcare CARESCAPE™ B650 Patient monitor (K131223)

• GE Healthcare CARESCAPE™ B450 Patient monitor (K132533)

• GE Healthcare B40 Patient monitor (K133576)

Intended Use (807.92(a)(5)):

The GE Healthcare Entropy module, E-ENTROPY, and accessories are indicated for adult and pediatric patients older than 2 years within a hospital for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. The Entropy algorithm in the host monitor calculates the spectral entropies, Response Entropy (RE) and State Entropy (SE), which are processed EEG and FEMG variables. The Entropy measurement is to be used as an adjunct to other physiological parameters.

In adult patients, Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may be associated with a reduction of anesthetic use and faster emergence from anesthesia.

The Entropy module is indicated for use by qualified

medical personnel only.

Technology (807.92(a)(6)): The proposed device in this document is the Entropy module, E-ENTROPY-01. The Entropy Module, E-ENTROPY together with a compatible host monitor forms a system for measuring patient entropy. The predicate device is the previously cleared Datex-Ohmeda S/5™ Entropy Module, E-ENTROPY-00, (K061907).

See comparison table in this section.

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
Intended Use Statements			
Indications for use	The Datex-Ohmeda Entropy module, E-ENTROPY, and accessories are indicated for adult and pediatric patients older than 2 years within a hospital for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. The spectral entropies, Response Entropy (RE) and State Entropy (SE), are processed EEG and FEMG variables. The Entropy measurement is to be used as an adjunct to other physiological parameters. In adult patients, Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may be associated with a reduction of anesthetic use and faster emergence from anesthesia. The Entropy module is indicated for use by qualified medical personnel only.	The GE Healthcare Entropy module, E-ENTROPY, and accessories are indicated for adult and pediatric patients older than 2 years within a hospital for monitoring the state of the brain by data acquisition of electroencephalograph (EEG) and frontal electromyograph (FEMG) signals. The Entropy algorithm in the host monitor calculates the spectral entropies, Response Entropy (RE) and State Entropy (SE), which are processed EEG and FEMG variables. The Entropy measurement is to be used as an adjunct to other physiological parameters. In adult patients, Response Entropy (RE) and State Entropy (SE) may be used as an aid in monitoring the effects of certain anesthetic agents, which may help the user titrate anesthetic drugs according to the individual needs of adult patients. Furthermore in adults, the use of Entropy parameters may be associated with a reduction of anesthetic use and faster emergence from anesthesia. The Entropy module is indicated for use by qualified medical personnel only.	Equivalent There are no actual changes compared to the predicate but just clarification that the Entropy algorithm resides in the monitor. This has no impact on substantial equivalence as compared to the predicate.
Measured Parameters and their specifications			
Patient age limit	The device is intended for adult and pediatric patients up from 2 years.	The device is intended for adult and pediatric patients up from 2 years.	Identical

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
General safety standards	IEC 60601-1:1988 + Amdt. 1:1991 + Amdt. 2:1995 EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996 CAN/CSA-C22.2 No. 601-M90 + S1:1194 + Amdt 2:1998 UL 2601-1:1997 IEC 60601-2-26:2002 EN 60601-2-26:2002 IEC 60601-1-2:2001 EN 60601-1-2:2001 IaEC 60601-1-4:1996 + Amd 1:1999 EN 60601-1-4:1996 + A1:1999	IEC 60601-1:1988 + Amdt 1:1991 + Amd 2:1995 EN 60601-1:1990 + A1: 1993 + A2: 1995 + A13:1996 CAN/CSA-C22.2 No. 601-M90 + S1:1194 + Amdt 2:1998 UL 60601-1:2003 IEC 60601-2-26:2002 EN 60601-2-26:2002 IEC 60601-1-2:2001 + A1:2004 EN 60601-1-2:2001 + A1:2006 IEC 60601-1-4:1996 + A1:1999 EN 60601-1-4:1996 + A1:1999	Equivalent UL 2601-1:1997 has been superseded by UL60601-1:2003 IEC 60601-1-2 has a new amendment A1:2004. EN 60601-1-2 has a new amendment A1:2006
Patient Monitor compatibility	Datex-Ohmeda S/5™ Anesthesia Monitor (K092680) Datex-Ohmeda S/5™ Compact Anesthesia Monitor (K061185)	Datex-Ohmeda S/5™ Anesthesia Monitor (K092680) Datex-Ohmeda S/5™ Compact Anesthesia Monitor (K061185) GE Healthcare CARESCAPE™ B850 Patient monitor (K131414) GE Healthcare CARESCAPE™ B650 Patient monitor (K131223) GE Healthcare CARESCAPE™ B450 Patient monitor (K132533) GE Healthcare B40 Patient monitor (K133576)	Equivalent New patient Monitors supporting Entropy have been introduced since Model E-ENTROPY-00 submission
Technical specifications			
Number of EEG channels	1 channel of raw EEG	1 channel of raw EEG	Identical

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
EEG measurement mode	Referential	Referential	Identical
Input dynamic range	±400 uV	±500 uV	Equivalent Model E-ENTROPY-01 has a slightly larger dynamic range but this has no impact on substantial equivalence as compared to the predicate. .
Input offset	±300 mV	±300 mV	Identical
Frequency range	0.5 to 118 Hz	0.5 to > 100 Hz	Equivalent The algorithm used to calculate Entropy values, Response Entropy and State Entropy, uses EEG frequencies which are within specification of both module models. This has no impact on substantial equivalence as compared to the predicate.
Noise	< 0.5 uV RMS	< 0.5 uV RMS	Identical

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
Noise (peak-to-peak)	Not specified	< 6 uV peak-to-peak	New specification added for Model E-ENTROPY-01 for peak-to-peak noise as required by IEC 60601-2-26 3rd edition section 201.12.1.101.3 Adding additional specifications has no impact on substantial equivalence as compared to the predicate. .

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
Input impedance	> 1 MΩ at 10 Hz	> 400 kΩ @10Hz	Substantially equivalent Essential Performance requirements from IEC 60601-2-26:2012 have been integrated to Model E-ENTROPY-01 Product Specifications. All Essential Performance requirements are fulfilled demonstrating EEG measurement performance. Input impedance specification change does not cause unwanted measurement error in EEG signal amplitude as 400 kΩ input impedance is significantly higher than the maximum allowed skin-electrode contact impedance (7.5kΩ) for Entropy measurement, This change has no impact on substantial equivalence as compared to the predicate.

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
Common mode rejection ratio	> 100 dB at 50 Hz	> 90 dB @ 50 Hz	Substantially equivalent The requirement and measurement method in the proposed device has been harmonized with IEC 60601-2-26 3rd edition section 201.12.1.101.5 and this slight change has no impact on substantial equivalence as compared to the predicate.
Defibrillation protection	3000V	3000V	Identical
Sampling frequency	400 Hz (1600 Hz with oversampling)	400 Hz (1600 Hz with oversampling)	Identical
Degree of protection against electrical shock	CF, defibrillation-proof	CF, defibrillation-proof	Identical
Electrode impedance measurement specifications			
Measurement frequency	75 Hz	75 Hz	Identical

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
Range	1 to 30 kΩ	1 to 20 kΩ	Equivalent Electrode impedance measurement values are not displayed to the end user. Internally the result is used to evaluate if the electrode impedance is low enough for reliable Entropy measurement. Limit in Entropy measurement is 7.5 kΩ. If the impedance is above that limit, a "check sensor" message is displayed and measurement is stopped. This decision limit (7.5 kΩ) is well within the specifications of both Entropy module models and this change to a 20 kΩ has no impact on substantial equivalence as compared to the predicate.
Resolution	0.1 kΩ	0.1 kΩ	Identical
Accuracy	±1 kΩ or ±10%	±1 kΩ or ±10%	Identical
Leads of detection	Continuous	Continuous	Identical
Start of impedance measurement	Manual / Automatic	Manual / Automatic	Identical
Compatible accessories			
Patient cable	GE Entropy Cable M1050784, 510(k) Number K062580	GE Entropy Cable M1050784, 510(k) Number K062580	Identical

Specification	Predicate Device Datex-Ohmeda S/5 Entropy Module, E-ENTROPY-00 K061907	Proposed Entropy module, E-ENTROPY-01	Discussion of Differences
Sensors	GE Entropy Sensor M1038681, 510(k) Number K082540 Entropy EasyFit Sensor M1174413, 510(k) Number K103129	GE Entropy Sensor M1038681, 510(k) Number K082540 Entropy EasyFit Sensor M1174413, 510(k) Number K103129	Identical

Determination of Substantial Equivalence (807.92(b)(1):

Summary of Non-Clinical Tests:

The ENTROPY MODULE, E-ENTROPY complies with voluntary standards as detailed below. The following quality assurance measures were applied in the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
-

The ENTROPY MODULE, E-ENTROPY was designed and tested for compliance to the following standards:

- IEC 60601-1:1988 + A1:1991 + A2:1995, Medical Electrical Equipment Part 1: General Requirements for Safety
- IEC 60601-1-2:2001 + A1:2004, Medical electrical equipment – Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 60601-1-2:2007, Medical electrical equipment - Part 1-2: General requirements for basic safety

and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

- IEC 60601-1-4:2000 Consol. Ed. 1.1 (IEC 60601-1-4:1996 + A1:1999), Medical electrical equipment - Part 1-4: General requirements for safety -- Collateral standard: Programmable electrical medical systems, edition 1.1. (General)
- IEC60601-1-6:2006, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – collateral Standard: Usability
- IEC60601-1-26:2002, Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs

  Except for the following clause:

  - Clause 17h: Defibrillation voltage 3kV is allowed to be used instead of 5kV in the differential mode test when testing the E-ENTROPY module.
  - The voltages between the electrodes of the sensor placed on the forehead can be assumed to be below 3kV (see Annex AA.1 in IEC 60601-2-26:2002).
- EN 980:2008, Symbols for use in the labeling of medical devices
- EN1041:2008, Information supplied by the manufacturer of medical devices

In addition to standards testing the ENTROPY MODULE, E-ENTROPY was also verified in other bench tests:

- The results of In-House system testing are summarized in test report DOC1221813 In-House Verification Report for E-Entropy-01 Module. Conclusion of the In-House system testing is: "All the verification activities planned in E-Entropy-01 program verification plan have been completed and the defect from the E-Entropy-01 database in ClearQuest have been verified and reviewed in DRB by the LSD and QA. Verification has PASSED."
- The usability validation performed according to DOC1208044 E-ENTROPY-01 Usability Validation Plan demonstrates that the usability and ergonomic design of

the Entropy Module, E-ENTROPY is acceptable to the intended users and therefore supports IEC 60601-1-6:2006 Medical electrical equipment. Part 1-6: General requirements for safety – Collateral standard: Usability. The results of usability testing are captured in DOC1261218 E-ENTROPY-01

- Software testing is described is described in the DOC1223430 E-ENTROPY-01 Verification Report
- Overall, a summary of the verification testing for the Entropy Module, E-ENTROPY is described in the DOC1223430 E-ENTROPY-01 Verification Report enclosed in the appendix. The conclusion is that satisfactory completion of the verification activity for the Entropy Module, E-ENTROPY has been achieved. The verification has passed based on the summary of results from the verification reports and the acceptance criteria defined in DOC1019758 E-Entropy-01 Verification Plan.

Summary of Clinical Tests:

Clinical (807.92(b)(2)): No additional clinical tests were performed for proposed ENTROPY MODULE, E-ENTROPY.

Conclusion (807.92(b)(3)): GE Healthcare considers the proposed ENTROPY MODULE, E-ENTROPY to be as safe, as effective, and performance is substantially equivalent to the predicate device.